CAPSTAR - nitenpyram tablet

Novartis Animal Health US, Inc.

Capstar®

(nitenpyram)

CAPSTAR® is an oral tablet for dogs, puppies, cats and kittens 4 weeks of age and older and 2 pounds of body weight or greater.

ACTIVE INGREDIENTS

CAPSTAR Tablets contain 11.4 or 57.0 mg of nitenpyram, which belongs to the chemical class of neonicotinoids. Nitenpyram kills adult fleas.

WARNINGS

Not for human use. Keep this and all drugs out of the reach of children.

DIRECTIONS

CAPSTAR Tablets kill adult fleas and are indicated for the treatment of flea infestations on dogs, puppies, cats and kittens 4 weeks of age and older and 2 pounds of body weight or greater.

A single dose of CAPSTAR should kill the adult fleas on your pet. If your pet gets re-infested with fleas, you can safely give another dose as often as once per day.

To give CAPSTAR Tablets, place the pill directly in your pet's mouth or hide it in food. If you hide the pill in food, watch closely to make sure your pet swallows the pill. If you are not sure that your pet swallowed the pill, it is safe to give a second pill.

Treat all infested pets in the household. Fleas can reproduce on untreated pets and allow infestations to persist.

DOSAGE

CAPSTAR Tablets should be administered according to the following schedule. **Weigh your pet prior to administration to ensure proper dosage**. Do not administer to pets under 2 pounds.

Recommended Dosage Schedule					
Species	Body Weight	Dose	Nitenpyram Per Tablet		
Dog or Cat	2-25 lbs.	One tablet	11.4 mg		
Dog	25.1-125 lbs.	One tablet	57.0 mg		

^{*}Please see separate insert in this package for concurrent dosing of CAPSTAR Tablets and PROGRAM® (lufenuron) Flavor Tabs®.

ADVERSE REACTIONS

Laboratory and clinical studies showed that CAPSTAR Tablets are safe for use in dogs and cats, puppies and kittens 4 weeks of age and older and 2 pounds of body weight or greater.

OTHER INFORMATION

CAPSTAR Tablets begin working within 30 minutes. In studies, CAPSTAR achieved greater than 90% effectiveness against adult fleas on dogs within 4 hours and cats within 6 hours.

CAPSTAR Tablets are safe for pregnant or nursing dogs and cats.

When using this product, you may notice that your dog or cat will start scratching itself as fleas begin to die. The scratching behavior is temporary and is a reaction to the fleas, not the drug. In very rare cases in cats, this may present as transient signs of hyperactivity, panting, vocalization and excessive grooming.

CAPSTAR Tablets kill adult fleas that cause flea allergy dermatitis (FAD).

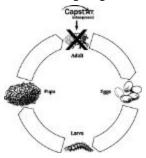
CAPSTAR Tablets may be used together with other products, including heartworm preventives, corticosteroids, antibiotics, vaccines, de-worming medications, shampoos and other flea products.

FLEA INFESTATIONS ON DOGS AND CATS

In addition to the common nuisance irritations associated with infestations, fleas can be responsible for skin conditions in your pet such as flea allergy dermatitis (FAD) in the dog and miliary dermatitis in the cat. Also, fleas transmit other parasites, including tapeworms. The control of flea infestations is important to your pet's health and also reduces the problems associated with these parasites.

CAPSTAR Tablets do not have an effect on fleas in the pet's environment. You may need to treat more than one time because immature fleas in and around the home will continue to develop into adults that can reinfest your pet.

In addition to killing adult fleas with CAPSTAR, you can treat your pet with an insect development inhibitor like PROGRAM Flavor Tabs to prevent and control flea populations. Please see the separate PROGRAM Flavor Tabs/CAPSTAR Tablets FLEA MANAGEMENT SYSTEM insert included in this package for information on how to use these two products together to kill adult fleas and prevent flea eggs from hatching. For information on how to use SENTINEL® (milbemycin oxime/lufenuron) Flavor Tabs® (for dogs only) with CAPSTAR Tablets, see your veterinarian. The following diagram illustrates the flea's life cycle and where CAPSTAR Tablets work:



Life Cycle of the Flea

Fleas can be a problem because they reproduce so rapidly. A single female flea may produce up to 2,000 eggs over her lifetime. Eggs hatch and can develop into adults within only three weeks. Adult female fleas feed by ingesting blood from your pet and subsequently lay eggs, which drop off your pet's coat. Within days, larvae hatch from the eggs and live undetected in your pet's surroundings, such as the carpet, bedding and other protected areas. Flea larvae spin a cocoon, and, when appropriately stimulated, a young adult flea emerges and jumps onto your pet to continue the life cycle. When these new fleas are seen on your pet, treat with CAPSTAR Tablets. After reading this insert, if you have any questions about flea control or medical problems associated with flea infestations, consult your veterinarian, who is your pet's health care expert.

STORAGE CONDITIONS

Store at controlled room temperature, between 59° and 77°F (15°-25°C).

Questions? Comments?

Please Call 1-800-332-2761

Visit our web site at www.petwellness.com

Manufactured for: Novartis Animal Health US, Inc.

Greensboro, NC 27408

NADA #141-175, Approved by FDA.

U.S. Patent # 5,750,548

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NAH/CAP-FMS/PI/302/08

CAPSTAR® (nitenpyram) PROGRAM® (lufenuron) Flavor Tabs®

FLEA MANAGEMENT SYSTEM

Supplemental Product Information

Information for Dosing Dogs

This insert describes the concurrent use of PROGRAM® (lufenuron) Flavor Tabs® and CAPSTAR® (nitenpyram)Tablets for the management of fleas on dogs and puppies.

Please read the insert contained in each package for complete information on the individual products prior to dosing.

WARNINGS

Not for human use. Keep this and all drugs out of reach of children.

DIRECTIONS

In dogs and puppies the concurrent use of PROGRAM Flavor Tabs and CAPSTAR Tablets is indicated to kill adult fleas and prevent eggs from hatching. The effects of PROGRAM Flavor Tabs, which prevent and control flea populations, and CAPSTAR Tablets, which treat flea infestations, are combined to provide a FLEA MANAGEMENT SYSTEM.

STEP 1: PREVENTION AND CONTROL

Give PROGRAM Flavor Tabs once per month to prevent and control flea populations. PROGRAM Flavor Tabs contain lufenuron. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. If a dog currently has a flea infestation, more rapid relief can be accomplished by adding CAPSTAR to the treatment as follows.

STEP 2: KILL ADULT FLEAS

If your pet currently has a flea infestation, use CAPSTAR Tablets to kill adult fleas. CAPSTAR Tablets contain nitenpyram and are effective for the treatment of flea infestations. Nitenpyram starts killing adult fleas within 30 minutes of administration.

- Administer CAPSTAR Tablets once per week until adult fleas are no longer observed.
- For a severe flea infestation, administer CAPSTAR Tablets twice per week until adult fleas are no longer observed.
- Additional CAPSTAR Tablets may be administered as needed to kill the occasional adult flea picked up from infested environments.
- It is important to treat all cats (see reverse side of this insert) and dogs in the household. Fleas can reproduce on untreated pets and allow infestations to persist.

DOSAGE

The combination of PROGRAM Flavor Tabs and CAPSTAR Tablets should be administered according to the following schedule. **Weigh the dog prior to administration to ensure proper dosage.** Do not administer to dogs under 2 pounds.

Recommended Dosage Schedule

Body Weight	Dose	CAPSTAR Once or twice weekly* (Nitenpyram per tablet)	PROGRAM Flavor Tabs once per month (Lufenuron per tablet)
2 to 10 lbs.	One tablet	11.4 mg	45.0 mg
11 to 20 lbs.	One tablet	11.4 mg	90.0 mg
21 to 25 lbs.	One tablet	11.4 mg	204.9 mg
26 to 45 lbs	One tablet	57.0 mg	204.9 mg
46 to 90 lbs.	One tablet	57.0 mg	409.8 mg
91 to 125 lbs.	One tablet	57.0 mg	**

^{*}If adult fleas are seen

ADVERSE REACTIONS

The following adverse reactions have been reported in dogs after giving PROGRAM Flavor Tabs: vomiting, depression/lethargy, pruritus (itchy, scratchy skin), urticaria (wheals, hives), diarrhea, anorexia (loss of appetite), and skin congestion (red skin).

OTHER INFORMATION

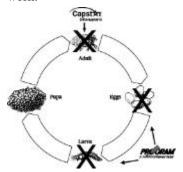
The safety of the concurrent use of lufenuron, the active ingredient in PROGRAM Flavor Tabs, and CAPSTAR Tablets has not been evaluated in puppies less than 11 weeks old.

FLEA INFESTATIONS ON DOGS

In addition to the common nuisance irritations associated with infestations, fleas can be responsible for skin conditions in the dog such as flea allergy dermatitis. Fleas also transmit other parasites, including tapeworms. The control of flea infestations is important to the pet's health and reduces the problems associated with these parasites.

PROGRAM Flavor Tabs break the flea life cycle by inhibiting egg development. CAPSTAR Tablets kill adult fleas on the dog. The concurrent use of these two products provides an effective flea management system.

The following diagram illustrates the flea's life cycle and where the combination of PROGRAM Flavor Tabs and CAPSTAR Tablets work:



Life Cycle of the Flea

^{**} Dogs over 90 lbs. are provided the appropriate combination of PROGRAM Flavor Tabs.

A single female flea may produce up to 2,000 eggs over her lifetime. Eggs hatch and can develop into adults within only three weeks. Adult female fleas feed by ingesting blood from the pet and subsequently lay eggs, which drop off the pet's coat. Within days, larvae hatch from the eggs and live undetected in the pet's surroundings, such as the carpet and bedding. Flea larvae spin a cocoon, and, when appropriately stimulated, a young adult flea emerges and jumps onto the pet to continue the life cycle.

After reading this insert, if you have any questions about the concurrent use of PROGRAM Flavor Tabs and CAPSTAR Tablets in your dogs, please call Novartis Animal Health US, Inc. Veterinary Product Support at 1(800)-332-2761.

STORAGE CONDITIONS

Store PROGRAM Flavor Tabs and CAPSTAR as described on the individual product inserts.

Ouestions? Comments?

Please Call 1-800-332-2761

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Greensboro, NC 27408

NADA #141-205, Approved by FDA.

U.S. Patent # 5,750,548

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CAPSTAR® (nitenpyram)

CAPSTAR® is an oral tablet for dogs, puppies, cats and kittens 4 weeks of age and older and 2 pounds of body weight or greater.

ACTIVE INGREDIENTS

CAPSTAR Tablets contain 11.4 or 57.0 mg of nitenpyram, which belongs to the chemical class of neonicotinoids. Nitenpyram kills adult fleas.

WARNINGS

Not for human use. Keep this and all drugs out of the reach of children.

DIRECTIONS

CAPSTAR Tablets kill adult fleas and are indicated for the treatment of flea infestations on dogs, puppies, cats and kittens 4 weeks of age and older and 2 pounds of body weight or greater.

A single dose of CAPSTAR should kill the adult fleas on your pet. If your pet gets re-infested with fleas, you can safely give another dose as often as once per day.

To give CAPSTAR Tablets, place the pill directly in your pet's mouth or hide it in food. If you hide the pill in food, watch closely to make sure your pet swallows the pill. If you are not sure that your pet swallowed the pill, it is safe to give a second pill.

Treat all infested pets in the household. Fleas can reproduce on untreated pets and allow infestations to persist.

DOSAGE

CAPSTAR Tablets should be administered according to the following schedule. Weigh your pet prior to administration to ensure proper dosage. Do not administer to pets under 2 pounds.

Recommended Dosage Schedule					
Species	Body Weight	Dose	Nitenpyram Per Tablet		
Dog or Cat	2-25 lbs.	One tablet	11.4 mg		
Dog	25.1-125 lbs.	One tablet	57.0 mg		

^{*}Please see separate insert in this package for concurrent dosing of CAPSTAR Tablets and PROGRAM® (lufenuron) Flavor Tabs®.

ADVERSE REACTIONS

Laboratory and clinical studies showed that CAPSTAR Tablets are safe for use in dogs and cats, puppies and kittens 4 weeks of age and older and 2 pounds of body weight or greater.

OTHER INFORMATION

CAPSTAR Tablets begin working within 30 minutes. In studies, CAPSTAR achieved greater than 90% effectiveness against adult fleas on dogs within 4 hours and cats within 6 hours.

CAPSTAR Tablets are safe for pregnant or nursing dogs and cats.

When using this product, you may notice that your dog or cat will start scratching itself as fleas begin to die. The scratching behavior is temporary and is a reaction to the fleas, not the drug. In very rare cases in cats, this may present as transient signs of hyperactivity, panting, vocalization and excessive grooming.

CAPSTAR Tablets kill adult fleas that cause flea allergy dermatitis (FAD).

CAPSTAR Tablets may be used together with other products, including heartworm preventives, corticosteroids, antibiotics, vaccines, de-worming medications, shampoos and other flea products.

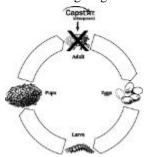
FLEA INFESTATIONS ON DOGS AND CATS

In addition to the common nuisance irritations associated with infestations, fleas can be responsible for skin conditions in your pet such as flea allergy dermatitis (FAD) in the dog and miliary dermatitis in the cat. Also, fleas transmit other parasites, including tapeworms. The control of flea infestations is important to your pet's health and also reduces the problems associated with these parasites.

CAPSTAR Tablets do not have an effect on fleas in the pet's environment. You may need to treat more than one time because immature fleas in and around the home will continue to develop into adults that can reinfest your pet.

In addition to killing adult fleas with CAPSTAR, you can treat your pet with an insect development inhibitor like PROGRAM Flavor Tabs to prevent and control flea populations. Please see the separate PROGRAM Flavor Tabs/CAPSTAR Tablets FLEA MANAGEMENT SYSTEM insert included in this package for information on how to use these two products together to kill adult fleas and prevent flea eggs from hatching. For information on how to use SENTINEL® (milbemycin oxime/lufenuron) Flavor Tabs® (for dogs only) with CAPSTAR Tablets, see your veterinarian.

The following diagram illustrates the flea's life cycle and where CAPSTAR Tablets work:



Life Cycle of the Flea

Fleas can be a problem because they reproduce so rapidly. A single female flea may produce up to 2,000 eggs over her lifetime. Eggs hatch and can develop into adults within only three weeks. Adult female fleas feed by ingesting blood from your pet and subsequently lay eggs, which drop off your pet's coat. Within days, larvae hatch from the eggs and live undetected in your pet's surroundings, such as the carpet, bedding and other protected areas. Flea larvae spin a cocoon, and, when appropriately stimulated, a young adult flea emerges and jumps onto your pet to continue the life cycle. When these new fleas are seen on your pet, treat with CAPSTAR Tablets. After reading this insert, if you have any questions about flea control or medical problems associated with flea infestations, consult your veterinarian, who is your pet's health care expert.

STORAGE CONDITIONS

Store at controlled room temperature, between 59° and 77°F (15°-25°C).

Questions? Comments?

Please Call 1-800-332-2761

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Greensboro, NC 27408

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NAH/CAP-FMS/PI/30

2/08

FLEA MANAGEMENT SYSTEM

Supplemental Product Information

Information for Dosing Cats

This insert describes the concurrent use of PROGRAM® (lufenuron) Flavor Tabs® and CAPSTAR® (nitenpyram)Tablets for the management of fleas on cats and kittens.

Please read the insert contained in each package for complete information on the individual products prior to dosing.

WARNINGS

Not for human use. Keep this and all drugs out of reach of children.

DIRECTIONS

In cats and kittens the concurrent use of PROGRAM Flavor Tabs and CAPSTAR Tablets is indicated to kill adult fleas and prevent eggs from hatching. The effects of PROGRAM Flavor Tabs, which control flea populations, and CAPSTAR Tablets, which treat flea infestations, are combined to provide a FLEA MANAGEMENT SYSTEM.

STEP 1: CONTROL

Give PROGRAM Flavor Tabs once per month to control flea populations. PROGRAM Flavor Tabs contain lufenuron. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. If a cat currently has a flea infestation, more rapid relief can be accomplished by adding CAPSTAR to the treatment as follows.

STEP 2: KILL ADULT FLEAS

If your pet currently has a flea infestation, use CAPSTAR Tablets to kill adult fleas. CAPSTAR Tablets contain nitenpyram and are effective for the treatment of flea infestations. Nitenpyram starts killing adult fleas within 30 minutes of administration.

- Administer CAPSTAR Tablets once per week until adult fleas are no longer observed.
- For a severe flea infestation, administer CAPSTAR Tablets twice per week until adult fleas are no longer observed.
- Additional CAPSTAR Tablets may be administered as needed to kill the occasional adult flea picked up from infested environments.
- It is important to treat all dogs (see reverse side of this insert) and cats in the household. Fleas can reproduce on untreated pets and allow infestations to persist.

DOSAGE

The combination of PROGRAM Flavor Tabs and CAPSTAR Tablets should be administered according to the following schedule. Weigh the cat prior to administration to ensure proper dosage. Do not administer to cats under 2 pounds.

Recommended Dosage Schedule

Body Weight	Dose	CAPSTAR Once or twice weekly* (Nitenpyram per tablet)	PROGRAM Flavor Tabs once per month (Lufenuron per tablet)
2 to 6 lbs.	One tablet	11.4 mg	90.0 mg
7 to 15 lbs.	One tablet	11.4 mg	204.9 mg
16 to 25 lbs.	One tablet	11.4 mg	**

^{*}If adult fleas are seen

ADVERSE REACTIONS

The following adverse reactions have been reported in cats after giving PROGRAM Flavor Tabs: vomiting, depression/lethargy, anorexia (loss of appetite), diarrhea, hyperactivity, dyspnea (labored breathing), pruritus (itchy skin), and skin eruptions (rash).

OTHER INFORMATION

The safety of the concurrent use of PROGRAM Flavor Tabs and CAPSTAR Tablets has not been evaluated in kittens less than 7 months of age.

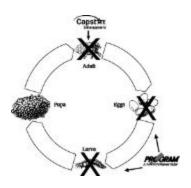
FLEA INFESTATIONS ON CATS

In addition to the common nuisance irritations associated with infestations, fleas can be responsible for skin conditions in the cat such as miliary dermatitis. Fleas also transmit other parasites, including tapeworms. The control of flea infestations is important to the pet's health and reduces the problems associated with these parasites.

PROGRAM Flavor Tabs break the flea life cycle by inhibiting egg development. CAPSTAR Tablets rapidly kill adult fleas on the cat. The concurrent use of these two products provides an effective flea management system.

The following diagram illustrates the flea's life cycle and where the combination of PROGRAM Flavor Tabs and CAPSTAR Tablets work:

^{**} Cats over 15 lbs. are provided the appropriate combination of PROGRAM Flavor Tabs.



Life Cycle of the Flea

A single female flea may produce up to 2,000 eggs over her lifetime. Eggs hatch and can develop into adults within only three weeks. Adult female fleas feed by ingesting blood from the pet and subsequently lay eggs, which drop off the pet's coat. Within days, larvae hatch from the eggs and live undetected in the pet's surroundings, such as the carpet and bedding. Flea larvae spin a cocoon, and, when appropriately stimulated, a young adult flea emerges and jumps onto the pet to continue the life cycle.

After reading this insert, if you have any questions about the concurrent use of PROGRAM Flavor Tabs and CAPSTAR Tablets in

STORAGE CONDITIONS

Store PROGRAM Flavor Tabs and CAPSTAR as described on the individual product inserts.

your cats, please call Novartis Animal Health US, Inc. Veterinary Product Support at 1(800)-332-2761.

Questions? Comments?

Please Call 1-800-332-2761

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PRINCIPAL DISPLAY PANEL

For treatment of flea infestations on dogs and cats

 $Capstar^{\mathbb{B}}$

(nitenpyram)

For Dogs

And Cats

2-25 lbs.

6 Tablets

(11.4 mg nitenpyram)

FAST ACTING

Begins Working

Within 30 Minutes

For Oral Use

NOVARTIS

ANIMAL HEALTH

NADA #141-175

Approved by FDA

Product# 61011



PRINCIPAL DISPLAY PANEL

For treatment of flea infestations on dogs

Capstar[®]

(nitenpyram)

For Dogs

Over 25 lbs.

6 Tablets

(57.0 mg nitenpyram)

FAST ACTING

Begins Working

Within 30 Minutes

For Oral Use

NOVARTIS

ANIMAL HEALTH

NADA #141-175

Approved by FDA

Product# 61021

